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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,217	07/11/2003	Akio Matsuda	1254-0229P	6837

2292 7590 01/04/2006

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,217	MATSUDA ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *10 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *1,2,8,12,14-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2 IDSs
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-45 are pending.

2. Response to restriction requirement filed 08/10/2005 is acknowledged. Applicant elected, with traverse, Group II, claims 3-7,9-11,13 and nucleic acid SEQ ID No. 88. Applicant argues that claims of Group XIX are directed to nucleic acid comprising a fragment of SEQ ID No. 88. However, such nucleic acid have different function (inhibition of protein expression) and different structure (containing sequence "corresponding" to a part of a polynucleotide of claim 3), and a reference teaching polynucleotide SEQ ID No. 88 will not teach or suggest polynucleotide of claim 23. Similarly, a reference teaching polynucleotide SEQ ID No. 88 will not teach or suggest products of claim 25. The restriction requirement is still deemed proper and is therefore made FINAL. Claims 1,2,8,12,14-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 1,2,8,12,14-45 and amendment of claims 3-7,9-11,13 to read on elected invention are requested.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See, for example, page 3,4. Applicant is requested to delete the embedded hyperlinks and/or other form of browser-executable codes in the specification. See MPEP § 608.01(b).

Claim Rejections - 35 U.S.C. § 101/ 112-1

The following is a quotation of the 35 U.S.C. § 101:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.
"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.
"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. The following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.
B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101.)
C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".
D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

See also the MPEP at §§ 2107 - 2107.02.

4. Claims 3-7,9-11,13 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The invention is drawn to isolated nucleic acids comprising sequence SEQ ID No. 88 or analogs thereof.

Utility of a polynucleotide is defined either by the utility of the polynucleotide itself or by utility of polypeptide it encodes. Specification addresses polypeptide SEQ ID No. 88 as having (an unidentified) homology to Toll/IL-1 receptor domain sequence, and as being localized in a number of tissues(p. 47). Further, the intracellular localization of protein SEQ ID No. 87 is addressed (p. 67). Identifying a polypeptide as having a limited homology to the claimed polypeptides does not indicate what function it might have. Assignment to a prior art family of polypeptides is generally insufficient to meet the utility requirement unless such assignment would allow the artisan to assign a specific and substantial use to the new member of the polypeptide family. Skolnick et al. (Trends in Biotech., 18(1):34-39, 2000) disclose that the skilled artisan is well aware

that assigning functional activities for any particular polypeptide or polypeptide family based upon sequence homology is inaccurate, in part because of the multifunctional nature of polypeptides (see, e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two polypeptides, only experimental research can confirm the artisan's best guess as to the function of the structurally related polypeptide (see in particular "Abstract" and Box 2). Thus, the homology-based assignment of the claimed polypeptide does not appear to provide evidence of a specific and substantial utility based on the knowledge of the skilled artisan and the data presented in the instant specification.

It is also said that that polypeptide SEQ ID No. 87 is expressed in various tissues including leukocytes, spleen, lung and uterus (p. 47). However, there is no nexus to any particular disease or condition that would demonstrate the utility of identifying said polypeptide in these tissues. After further research, specific and substantial utility might be found for claimed polypeptide. This further characterization, however is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. As such, further research would be required. See Brenner v. Manson, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966), the court indicates "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." A patent is therefore not a license to experiment. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth, credibility of any utility cannot be assessed. The basic

quid pro quo of the patent system, as interpreted by the Brenner Court, is the grant of a valuable legal right in exchange for a meaningful disclosure of the claimed invention.

Further, even if the nucleotide of SEQ ID No. 88 had a demonstrated utility, there is no specific or substantial utility either for its fragments or for its homologs because no structural requirements for [a presumed] utility of these fragments or homologs are identified.

The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter. Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

5. Claims 3-7,9-11,13 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 3-6 are rejected under 35 U.S.C. 102(e) as being anticipated by the sequence SEQ ID No. 15 of US 200030012966. The referenced sequence shows 99% similarity to SEQ ID No. 88 of the instant invention (see attached sequence alignment). Therefore, the referenced polynucleotide reads on the polynucleotides of claims 3-6 which have at least one substitution in SEQ ID No. 88. Further, as the referenced sequence has continuous stretches matching the claimed sequence of SEQ ID No. 88, it would be expected to hybridize to SEQ ID No. 88 under high stringency conditions absent evidence to the contrary.

Conclusion.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb